IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIAN JOSEPH GREF, **Plaintiff,** **v.** **AMERICAN INTERNATIONAL INDUSTRIES, *et al.*,** **Defendant.**	**No. 1:20-cv-005589-GBD-DCF** **CONSOLIDATED REPLY TO SUBPOENAING DEFENDANTS' RESPONSES IN OPPOSITION TO NON-PARTY NORTHWELL HEALTH, INC.'S MOTION TO MODIFY SUBPOENAS**

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Pursuant to Federal Rule of Civil Procedure 45(d)(3), Local Civil Rules 6.1(a) and 7.1, and Your Honor's Individual Rules, non-party Northwell Health, Inc. ("Northwell") hereby replies to Defendants American International Industries, Inc.'s ("AII") and Whittaker, Clark & Daniels, Inc.'s ("WCD") (together, "Subpoenaing Defendants") respective responses in opposition ("Responses," ECF Nos. 279, 280) to Northwell's motions to modify the subpoenas served by Subpoenaing Defendants ("Motions to Modify," ECF Nos. 264 and 267).

I. INTRODUCTION

Among its many activities, Northwell—a non-party to this litigation—funds scholarly research, including through its Department of Occupational Medicine, Epidemiology and Prevention (the "Department"). This Department pursues an "overall mission . . . to provide, understand and prevent diseases through exemplary patient care and innovative population-based research, with a special interest on exposure-based conditions." *See* Website, Northwell Health, Occupational Medicine, Epidemiology and Prevention, https://www.northwell.edu/occupational-medicine-epidemiology-prevention.

In 2019, Dr. Jacqueline Moline, Kristin Bevilacqua, MPH, Maya Alexandri, JD, and Ronald Gordon, Ph.D co-authored the article entitled, "Mesothelioma Associated with the Use of Cosmetic Talc" (the "Article"). (ECF No. 265-1, pp. 8-14) Contrary to Subpoenaing Defendants' multiple assertions that the Article exists solely to benefit the plaintiff's bar in product liability cases (*see* ECF No. 279, pp. 5, 20, 23), Northwell sanctioned this Article to advance the Department's overall mission (*see* ECF No. 265-1, p. 8 (indicating the Article is "[f]rom the Northwell Health Department of Occupational Medicine Epidemiology and Prevention.")). In fact, the Article transparently lists under "Conflicts of Interest" that "Authors J.M. and R.G. have served as expert witnesses in asbestos litigation, including talc litigation for plaintiffs." (*Id.*) The

Article's takeaways are that exposure to asbestos-contaminated cosmetic talc can cause mesothelioma, and that clinicians should elicit a history of talcum powder usage in all patients presenting with mesothelioma. (*Id.*) The authors found it clinically significant that cosmetic talc "may help explain the high prevalence of idiopathic mesothelioma cases, particularly among women." (*Id.*) Thus, the Article fits squarely within the Department's charge: seeking to "understand and prevent diseases through . . . innovative population-based research."

To be clear, Northwell has no vested interest in the outcome of this product liability litigation. Its sole aim is to protect the integrity of its Human Research Protection Program ("HRPP"), Institutional Review Board ("IRB"), and the Department. Again, prior to drafting the Article, Dr. Moline secured approval from Northwell's HRPP through the IRB, which approval Northwell granted on March 23, 2018. (ECF No. 265-6, pp. 3-4, ¶¶ 10, 17) As a condition for funding the research, Northwell's IRB required that Dr. Moline's research be conducted in accordance with, *inter alia*, 45 C.F.R. § 46 and the Health Insurance Portability and Accountability Act ("HIPAA"). (*Id.*, p. 4, ¶ 20) The Article was peer-reviewed and ultimately published in the Journal of Occupational and Environmental Medicine. (ECF No. 282, Ex. 6)

Subpoenaing Defendants posture this discovery dispute as the dispositive issue in this protracted litigation. By fixating on uncovering the identities of the Research Subjects—a tactic already dispensed with by several other courts (*see* ECF Nos. 265-4, -5)—it is Subpoenaing Defendants, not Northwell, who "seek[] to consume the resources of this Court to try to get a different result." (ECF No. 279, p. 4) In effect, they seek to conduct 33 mini-trials on causation—one for each Research Subject—in an attempt to discredit Dr. Moline's opinions. These efforts are disproportional to the needs of the case, and should not be countenanced by the Court. Dr. Moline was retained as an expert in this case several years after publication of the Article, and it

is only one of 492 items which forms the basis for her expert opinions. (ECF No. 282, pp. 7, 16) Subpoenaing Defendants already possess ample fodder to effectively cross-examine Dr. Moline and, if appropriate, to pursue a *Daubert* challenge. Given these circumstances, the Court should grant Northwell's Motions to Modify.

II. ARGUMENT

A. Collateral Estoppel Does Not Bar Northwell's Motions to Modify.

Subpoenaing Defendants contend that Northwell is collaterally estopped from protecting the Research Subjects' identities. Not so. There are vast differences between *Bell* and this case; thus, collateral estoppel simply does not apply. If it did, it would *support* Northwell's Motions to Modify and estop *Subpoenaing Defendants* from discovering the information they seek to compel.

1. Collateral Estoppel Does Not Apply Here.

As referenced in prior filings, with one exception, AII and others have unsuccessfully tried in multiple cases to uncloak the Research Subjects. (ECF No. 266, pp. 6-7) Subpoenaing Defendants successfully uncovered one of the 33 Research Subjects in *Bell v. Am. Int'l Indus.*, No. 1:17-cv-00111 (M.D.N.C. July 2021). They now rely on *Bell* in an attempt to unmask all 33 Research Subjects, arguing that "Northwell must be estopped from making the same arguments to this Court, seeking a contrary result." (ECF No. 279, p. 2) But as they acknowledge, the threshold requirement for the application of collateral estoppel is that "the issues in both proceedings [be] identical." (ECF No. 279, p. 3 (citing *Lord v. Int'l Marine Ins. Servs.*, 420 F. App'x 40, 41 (2d Cir. 2011)). And the issues in these two proceedings are far from identical.

For starters, the scope of discovery at issue here is much broader than in *Bell*. There, the issue before the court was whether Northwell should be compelled to produce "a single five-page document." (ECF No. 279-1, p. 7) In contrast, Subpoenaing Defendants here seek a wide-ranging

array of information, including compensation records, correspondence, records, communications, and other documents. (*See* ECF Nos. 265-1, -2) The *Bell* court found the narrow scope of the discovery sought weighed in favor of production. (ECF No. 279-1, p. 39 ("[T]his court notes that AII seeks . . . to unshield a single document. . . . While courts may be inclined to reject motions to vacate protective orders when a large number of documents would be 'wholesale release[d],' 'request[s] for modification only involv[ing] a limited set of documents' are more palatable.'" (quoting *SmithKline Beecham Corp. v. Synthon Pharms., Ltd.*, 210 F.R.D. 163, 168 (M.D.N.C. 2002)))). A different dynamic is present here.

Not only is the scope of discovery broader in this case; Subpoenaing Defendants seek distinctly different information than that ordered to be produced in *Bell*. There, the subject document was "a spreadsheet containing information on all thirty-three individuals studied [in the Article]." (ECF No. 279-1, p. 7) Notably, "the entire document [wa]s redacted except for the row heading and the column listing Mrs. Bell's information." (*Id.*) Subpoenaing Defendants did not seek for Northwell to remove the redactions from the document—thereby unmasking the Research Subjects—and the court did not address that issue. (*See* ECF No. 279-1) In contrast, they now seek the "[s]preadsheet in possession of Northwell identifying the 33 subjects of [the Article], which lists the subjects' first and last names, brand(s) of talc they used, law firm representation, occupation(s), and date of diagnosis and/or date of birth." (*See* ECF No. 265-1, p. 6; ECF No. 265-2, p. 7) Thus, unlike in *Bell*, the identities of all 33 Research Subjects are at issue here; not just Ms. Bell's. Subpoenaing Defendants admit as much in their Responses, noting:

> In *Bell*, counsel for plaintiff and Northwell made confidentiality and privilege arguments, including concerns about HIPAA and "human research" confidentiality, to shield Moline's Article from full and fair cross-examination. The *Bell* court rejected those arguments and

> ordered unsealed all information ***relating to Mrs. Bell*** as a subject of the study.

(ECF No. 279, p. 4 (emphasis supplied))

Additionally, the *Bell* court permitted Ms. Bell's identification as a Research Subject on the strength of factors that simply are not present here: (1) she was a party to the litigation and had thus placed her identity as a Research Subject—along with other information—squarely within the realm of discoverability, and (2) she no longer qualified as a "human subject" under 45 C.F.R. § 46.111(a)(7) given that she had passed during the pendency of the litigation. (ECF No. 279-1, pp. 31-34) She also voluntarily executed a HIPAA waiver authorizing Northwell to identify her as a Research Subject. (*Id.*, p. 7) None of these facts exist here. Much the opposite, Plaintiff Gref's counsel in this case notes that, unlike the plaintiff in *Bell*, "there is no possibility that Mr. Gref was a subject of Dr. Moline's Study." (ECF No. 282, p. 13)

Nevertheless, Subpoenaing Defendants contend that "the Motion[s] to Modify attempt[] to hide the identity of the participants of Dr. Moline's Article using the exact arguments Northwell used in *Bell* . . . ." (ECF No. 279, p. 4) However, as illustrated, the issues here are far from identical, as is required for collateral estoppel to attach. For the same reason, the cases Subpoenaing Defendants have marshalled in their Responses are inapposite. Collateral estoppel is no bar to Northwell's Motions to Modify.

2. If Collateral Estoppel Did Apply, it would Support Northwell's Motions to Modify and Preclude Subpoenaing Defendants from Discovering the Information They Seek to Compel.

Assuming *arguendo* that Subpoenaing Defendants have established that the issue before this Court is identical to that litigated to conclusion in *Bell*, all this proves is that Subpoenaing

Defendants are not entitled to the documents they seek. Indeed, if *Bell* collaterally estops anything, it is Subpoenaing Defendants' improper attempts to uncloak the Research Subjects.

If *Bell* is read—as Subpoenaing Defendants advocate—as conclusively determining the Research Subjects' entitlement to anonymity, it is Subpoenaing Defendants who are precluded from seeking to discover their identities. In selectively quoting from the *Bell* court's order, Subpoenaing Defendants gloss over the following analysis on the subject:

> United States Department of Health and Human Services regulations confer upon "human subject" research confidentiality protections enforced by an IRB. *See, e.g.*, 45 C.F.R. § 46.111(a)(7) (2020). "Human subject" is defined as "a living individual about whom an investigator . . . conducting research . . . [o]btains information . . . through intervention or interaction with the individual, and uses, studies, or analyzes the information or . . . [o]btains, uses, studies, analyzes, or generates identifiable private information." *Id.* § 46.102(e)(1) (emphasis added).
>
> . . . **[I]t seems likely that some of the other individuals the article studied were living when IRB approval was granted—thus qualifying them as human subjects**. Indeed, Northwell claims at least twenty three individuals studied were still living when the study was conducted. Irrespective of the exact number of living individuals, the fact that at least some of the individuals studied were alive when the IRB reviewed the article's application is corroborated by the IRB approval's statement that the "research must be conducted in accordance with . . . Department of Health and Human Services regulations CFR 46," which provides protection for human research subjects.
>
> Thus, **although the article as a whole likely qualified as human subject research**, Mrs. Bell herself was never a human subject because she was deceased by the time the study began. While being part of a larger study **that qualified as human subject research** may have facially and incidentally granted Mrs. Bell greater confidentiality protections, this court is hesitant to give much weight to those protections that were not crafted with the goal of protecting the privacy of deceased individuals like Mrs. Bell. . . .
>
> . . .

> Critically, the Northwell Document redacts all information on other individuals, **some of whom likely qualify as human subjects thus entitling them to greater confidentiality protections than Mrs. Bell**. . . .

(ECF No. 279-1, pp. 33-37 (emphases supplied) (cleaned up)) To the extent *Bell* collaterally estops Northwell from protecting the identities of the Research Subjects at all, it does so only with respect to Ms. Bell. And it also collaterally estops Subpoenaing Defendants from discovering the identities of any other Research Subjects, which the *Bell* court did not order revealed.

B. Contrary to Subpoenaing Defendants' Assertion, the Research Subjects' Identities are Privileged and Confidential.

Subpoenaing Defendants miss the mark in arguing that the Research Subjects are not entitled to anonymity. They erroneously contend that "the *Bell* court explicitly rejected 'The Common Rule' applied to the . . . Article." (ECF No. 279, p. 10) Not so. Even setting aside the fact that the excerpted portion of the Order that the Subpoenaing Defendants quote is dicta contained in a footnote, the court elsewhere in the Order states that "the article as a whole likely qualified as human subject research" entitled to Common Rule protection. (ECF No. 279-1, p. 35) And regardless of whether Northwell "voluntarily elected, as part of its 'Federalwide Assurance' to the government," to apply Common Rule protections to all research regardless of the source of support or funding for that research, the fact remains that Northwell has represented to the federal government that it will undertake to apply such protections. (*Id.*) On this point, Subpoenaing Defendants unsuccessfully attempt to distinguish the Second Circuit's holding in *In re Am. Tobacco Co.*, 880 F.2d 1520, 1522-23 (2d Cir. 1989), and in doing so point out that the physician there "assured his subjects that the information they provided would remain confidential." (ECF No. 279, pp. 22-23) This does not distinguish *American Tobacco* at all; rather, it illustrates why modification is appropriate here. Both Northwell and the physician there made assurances that

confidentiality would be observed. That these assurances were made to the federal government and the research subjects, respectively, is of no moment. Confidentiality was promised; confidentiality must be provided.

Subpoenaing Defendants also errantly suggest that the *Bell* court ruled that the IRB approval did not confer confidentiality on the Research Subjects. (ECF No. 279, pp. 10-11) Again, not so. What that court actually said was that "[t]he Northwell Document redacts all information on other individuals, some of whom likely qualify as human subjects thus entitling them to greater confidentiality protections than Mrs. Bell." (ECF No. 279-1, p. 37) And, again, Northwell has represented that it will afford such confidentiality protections to the Research Subjects. The court's ruling was only as to Ms. Bell; it found that she was not entitled to such protections, having passed away and no longer meeting the definition of "human research subject." (*Id.*, p. 35) The same cannot be said for the other Research Subjects.

And contrary to Subpoenaing Defendants' suggestion that "disclosing the identifies of the subjects of [the] Article would [not] have a 'chilling' effect' [on Northwell's future] human subject research," (ECF No. 279, p. 11), the *Bell* court confirmed that it "remains ever 'cognizant that "the ability to conduct probing scientific and social research supported by a population willing to submit to in-depth questioning" depends on the guarantee that the researcher will take steps to ensure confidentiality."'" (ECF No. 279-1, p. 36 (quoting *Farnsworth v. Procter & Gamble Co.*, 758 F.2d 1545, 1547 (11th Cir. 1985))) While the court opined that the chilling effect was ameliorated by the fact that the IRB did not require the authors to obtain informed consent from the individuals studied (*id.*), this does not alter the fact that Northwell has undertaken—and promised the federal government—that it will afford Common Rule protections to the Research Subjects. Far from "disingenuous," (ECF No. 279, p. 19), if prospective study participants learned

that Northwell was compelled to divulge participants' identities in other studies, they very well may decline to participate, directly undermining the Department's ability to conduct "innovative population-based research."

As for HIPAA, Northwell is a "covered entity" and subject to HIPAA's Privacy Rule. 45 C.F.R. §§ 160.103; 164.502(a). Northwell may use in its research PHI "that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual." 45 C.F.R. § 164.514(a); *see also id.* at §§ 164.502(d)(2); 164.512(i); 164.514(b). Subpoenaing Defendants' contention that "Dr. Moline was free to disregard those protections when she used the information" (ECF No. 279, p. 12) is incorrect; to the contrary, she used de-identified PHI as permitted under the Privacy Rule. *See* 45 C.F.R. § 164.514(a) Likewise, the fact that the Research Subjects filed complaints to recover for their mesotheliomas does not serve as a blanket HIPAA waiver allowing their statuses to be used at the whim of other litigants. *See* 45 C.F.R. §§ 164.508(a), (c)(1)(iv).

Subpoenaing Defendants profess a need to use the Research Subjects' identifies and PHI in future cross examination(s) of Dr. Moline or in a potential *Daubert* motion. But their Responses demonstrate that they already have ample fodder to cross-examine Dr. Moline about the Article and are therefore not prejudiced by the continued protection of this information. In *Bell*, Subpoenaing Defendants represented that "the purpose of [their] motion [to vacate the protective order prohibiting the identification of Ms. Bell as a Research Subject in proceedings outside the *Bell* litigation] [wa]s 'to prevent Moline and others from misrepresenting . . . the truth about a study supposedly showing that cosmetic talc causes mesothelioma,'" such that they would "be able to show that at least one of the individuals the article studied, Mrs. Bell, 'had alternative exposures to asbestos at her job sites.'" (ECF No. 279-1, pp. 15-16) As the *Bell* court noted, "[i]n essence,

[Subpoenaing Defendants] s[ought] to vacate the protective order so the Northwell Document [identifying Ms. Bell, and only Ms. Bell] can be used in other litigation." (ECF No. 279-1, p. 17) Given that they have confirmed Ms. Bell's identity as a Research Subject, Subpoenaing Defendants can freely employ this tactic; they do not need to uncloak the remaining Research Subjects in order to do so. Again, the Article is one of 492 items which forms the basis for Dr. Moline's expert opinions. (ECF No. 282, pp. 7, 16) Subpoenaing Defendants need not conduct 33 causation mini-trials to impeach Dr. Moline, and this Court should not allow them to trample over the Research Subjects' Common Rule protections to do so.

III. CONCLUSION

The Federal Rules of Civil Procedure are not permissive on the issue of subpoena modification. Rather, "[o]n timely motion, the court . . . ***must*** . . . modify a subpoena that . . . requires disclosure of privileged or other protected matter, if no exception or waiver applies . . . ." Fed. R. Civ. P. 45(d)(3)(A)(iii) (emphasis supplied). In its Motions to Modify and supporting documents (as well as in this Reply), Northwell has established that the Subpoenas "require[] disclosure of privileged or other protected matter," and Subpoenaing Defendants have failed to demonstrate that any "exception or waiver applies." *Id.* As shown herein, Subpoenaing Defendants have also come up short of showing that Northwell is collaterally estopped from modifying the Subpoenas, or that the Research Subjects are not entitled to anonymity. As such, Northwell respectfully requests that the Court grant its motions to modify the Subpoenas.

This the 2nd day of December, 2022.

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